# Decision Memo for Pulmonary Rehabilitation (CAG-00356N)

## Decision Summary

On December 27, 2006, we initiated the national coverage determination (NCD) process by opening a tracking sheet for Pulmonary Rehabilitation (PR) (CAG-00356N). After examining the available medical evidence, we have determined that no national coverage determination is appropriate at this time, and that decisions pursuant to § 1862(a)(1)(A) should be made by local contractors through the local coverage determination process or by case-by-case adjudication. See Heckler v. Ringer, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003).

Although services that make up pulmonary rehabilitation individually may be covered under Medicare and fall into various applicable benefit categories, CMS has determined that the Social Security Act does not expressly define a comprehensive Pulmonary Rehabilitation Program as a Part B benefit. In addition, as we noted, respiratory therapy services are identified as covered services under the Comprehensive Outpatient Rehabilitation Facility (CORF) benefit and defined in 42 CFR § 410.100(e)(1) to (2)(vi). In our proposed decision memorandum, we proposed to cover nationally those services identified in 42 C.F.R. § 410.100(e)(1) to (2)(vi) for Medicare beneficiaries with chronic obstructive pulmonary disease (COPD). Furthermore, we requested comments on the frequency and duration of the respiratory therapy services identified in 42 CFR §410.100(e)(1) to (2)(vi). We have determined, however, that the evidence is not adequate to draw conclusions about the frequency or duration of these CORF services. Therefore, we are not making a national coverage determination at this time. Accordingly, local contractors may continue to make decisions under § 1862(a)(1)(A), with regard to services related to pulmonary rehabilitation, through the local coverage determination process or on a case-by-case basis.

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## Decision Memo

TO: Administrative File: CAG 00089R

FROM: Steve E. Phurrough, MD, MPA
Director, Coverage and Analysis Group

Marcel Salive, MD, MPH
Director, Division of Medical and Surgical Services

Roya Lotfi
Lead Analyst, Division of Medical and Surgical Services

Ross J Brechner, MD, MS (Stat), MPH
Lead Medical Officer, Division of Items and Devices

SUBJECT: Coverage Decision Memorandum for Pulmonary Rehabilitation (PR) Services

DATE: September 25, 2007

**I. Decision**

On December 27, 2006, we initiated the national coverage determination (NCD) process by opening a tracking sheet for Pulmonary Rehabilitation (PR) (CAG-00356N). After examining the available medical evidence, we have determined that no national coverage determination is appropriate at this time, and that decisions pursuant to § 1862(a)(1)(A) should be made by local contractors through the local coverage determination process or by case-by-case adjudication. See Heckler v. Ringer, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003).

Although services that make up pulmonary rehabilitation individually may be covered under Medicare and fall into various applicable benefit categories, CMS has determined that the Social Security Act does not expressly define a comprehensive Pulmonary Rehabilitation Program as a Part B benefit. In addition, as we noted, respiratory therapy services are identified as covered services under the Comprehensive Outpatient Rehabilitation Facility (CORF) benefit and defined in 42 CFR § 410.100(e)(1) to (2)(vi). In our proposed decision memorandum, we proposed to cover nationally those services identified in 42 C.F.R. § 410.100(e)(1) to (2)(vi) for Medicare beneficiaries with chronic obstructive pulmonary disease (COPD). Furthermore, we requested comments on the frequency and duration of the respiratory therapy services identified in 42 CFR §410.100(e)(1) to (2)(vi). We have determined, however, that the evidence is not adequate to draw conclusions about the frequency or duration of these CORF services. Therefore, we are not making a national coverage determination at this time. Accordingly, local contractors may continue to make decisions under § 1862(a)(1)(A), with regard to services related to pulmonary rehabilitation, through the local coverage determination process or on a case-by-case basis.

**II. Background**

COPD is a term referring to two lung diseases, chronic bronchitis and emphysema, that are characterized by obstruction of airflow that interferes with normal breathing. Both of these conditions frequently co-exist, so physicians use the term COPD. It does not include other obstructive diseases such as asthma. The National Center for Health Statistics (NCHS) reports that COPD is the fourth leading cause of death in America, claiming the lives of 122,283 Americans in 2003. The number of women dying from the disease has surpassed the number seen in men (NCHS, 2003). The best prevalence data available at present come from the third NHANES (NHANES III), a large national survey conducted in the USA between 1988 and 1994. In the USA, for those aged 25-75 yrs, the estimated prevalence of mild COPD (defined as FEV1/FVC <70% and FEV1 ≥80% predicted) was 6.9% and of moderate COPD (defined as FEV1/FVC <70% and FEV1 ≤80% predicted) was 6.6%. The prevalence of both mild and moderate COPD was higher in males than females, in Whites than in Blacks, and increased steeply with age (Manino, 2002). In the NHANES III study, COPD (defined as the presence of airflow limitation) was estimated to be present in 14.2% of current White male smokers, 6.9% of exsmokers and 3.3% of never-smokers. Among White females, the prevalence of airflow limitation was 13.6% in smokers, 6.8% in ex-smokers and 3.1% in never-smokers.

COPD often has its roots decades before the onset of symptoms (Anto et al., 2001). Impaired growth of lung function during childhood and adolescence, caused by recurrent infections or tobacco smoking, may lead to lower maximally attained lung function in early adulthood (Gold et al., 1996). This abnormal growth, often combined with a shortened plateau phase in teenage smokers, will increase the risk of COPD. The landmark study of the natural history of COPD by Fletcher and Peto reported that the forced expiratory volume (FEV1) declined continuously and smoothly over time, with a slight acceleration of the rate of decline with aging. They showed that nonsmokers lose $FEV_1$ at a slow rate of approximately 42 mL/y and that in many smokers who are resistant to the deleterious effects of smoking on lung function, $FEV_1$ declines as slowly as in nonsmokers. In contrast, so-called "susceptible" smokers lose $FEV_1$ at an accelerated rate and are destined to go on to develop clinically significant airflow obstruction. (Fletcher et al., 1976)

Management of stable COPD (ATS American Thoracic Society Guidelines) is accomplished in part through the following modalities:

1. Smoking Cessation
2. Pharmacological Therapy

a. The medications for chronic obstructive pulmonary disease (COPD) currently available can reduce or abolish symptoms, increase exercise capacity, reduce the number and severity of exacerbations, and improve health status.
b. At present, no treatment is shown to modify the rate of decline in lung function.
c. The change in lung function after brief treatment with any drug does not help in predicting other clinically related outcomes.
d. The inhaled route is preferred.
e. Changes in forced expiratory volume in one second (FEV1) following bronchodilator therapy can be small but are often accompanied by larger changes in lung volume, which contribute to a reduction in perceived breathlessness.
f. Combining different agents produces a greater change in spirometry and symptoms than single agents alone. 3. Long-Term Oxygen Therapy
4. Pulmonary Rehabilitation
5. Nutrition counseling
6. COPD surgery
7. Evaluation and treatment of sleep disorders

In general PR may involve some or all of the following: treatment plans and implementation; medical evaluation; monitoring of progress; counseling and/or education; exercise training; self-management training; nutrition training; and psychosocial support.

## III. History of Medicare Coverage

### Medicare Coverage for Pulmonary Rehabilitation

Currently, there is no national coverage determination for PR. However, there is limited coverage for some respiratory therapy services provided in a comprehensive outpatient rehabilitation facility (CORF). Various components of PR also may be covered at contractor discretion in other settings.

### Reconsideration

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR), the American College of Chest Physicians (ACCP), the American Thoracic Society (ATS), and the National Association for Medical Direction of Respiratory Care (NAMDRC) formally requested that CMS promulgate an NCD which identifies the components of PR services. The requestors suggest that this NCD should address the provision of these services in the hospital outpatient setting, the physician office setting and the CORF setting.

### Benefit Category

There is no specific benefit category for, and no statutory definition of, "pulmonary rehabilitation" under Title XVIII of the Social Security Act (“the Act”). The CORF benefits may include “respiratory therapy” services and “pulmonary rehabilitation techniques” under a plan of treatment established and periodically reviewed by a physician (sections 1861(cc)(1), 1832(a)(2)(E) of the Act; 42 CFR section 410.100(e)). These CORF services must be furnished by qualified professional personnel as defined in regulation by the Secretary (42 CFR section 410.100).

Apart from the CORF benefit, other components of PR may be covered in different settings. For instance, physician evaluation and management (E/M) of patients with pulmonary diseases for whom "pulmonary rehabilitation" is contemplated may include an initial evaluation, treatment plan development and implementation, monitoring, and counseling/education regarding all aspects of the disease (42 CFR section 410.20). These E/M services may be considered to be a benefit as physicians' services under sections 1861(s)(1) and 1861(q) of the Act.

There may be a benefit category for therapeutic exercise under certain circumstances. For instance, therapeutic exercise may be considered to be a benefit under section 1861(p) of the Act as an outpatient physical therapy service.

In accordance with the provisions in section 1861 (q) of the Act which include professional services performed by physicians including consultation, physicians are authorized to furnish certain counseling services. Nurse practitioners, clinical nurse specialists, and physician assistants are also authorized by sections 1861(s)(2)(K)(ii) and (s)(2)(K)(i), respectively, of the Act to furnish services that would be physician services if performed by a physician that may include counseling services (42 CFR sections 410.75(c), 410.76(c), 410.74(a)(1)). Qualified psychologist services, which may often include counseling services, are authorized by section 1861(s)(2)(M) of the Act (42 CFR section 410.71). Counseling may be considered to be a benefit under section 1861(s)(2)(A) of the Act as “incident to” a physician service. If counseling services are related to a mental health diagnosis, then Clinical Social Workers are authorized by sections 1861(s)(2)(N) and 1861(hh) of the Act to furnish diagnostic and therapeutic mental health services that may include therapy services.

There is no general benefit category for nutritional counseling. We do not pay for the services of a registered dietician or professional nutritionist except under specified circumstances. Under section 1861(vv) of the Act, medical nutrition therapy is a covered benefit when furnished by a registered dietitian or professional nutritionist for certain individuals. The benefit covers nutritional diagnostic, therapy, and counseling services for the purpose of disease management for beneficiaries who are diabetic or have a renal disease, when a referral is made by a physician. It also allows registered dietitians and professional nutritionists to receive direct Medicare payment (42 CFR section 410.132). Under section 1861(q) of the Act, physicians’ services means professional services furnished by physicians, including consultation, and may include diet counseling, to the extent it falls within the physician’s scope of practice.

All services furnished under the Medicare program must be medically reasonable and necessary, and appropriate for diagnosis and/or treatment of an illness or injury.

**IV. Timeline**

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| December 27, 2006 | CMS accepts the American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR), the American College of Chest Physicians (ACCP), the American Thoracic Society (ATS), and the National Association for Medical Direction of Respiratory Care's (NAMDRC) formal request that CMS promulgate an NCD which identifies the components of PR services. The requestors suggest that this NCD should address the provision of these services in the hospital outpatient setting, the physician office setting and the CORF setting. |
| January 27, 2006 | Initial 30-day public comment period closes. |
| June 27, 2007 | Proposed decision memorandum is posted and the 30-day public comment period begins. |
| (Posting Date) | Final Decision memorandum is posted. |

**V. FDA Status**

Not Applicable.

**VI. General Methodological Principles**

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendices. In general, features or clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain personal health information will not be made available to the public. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

**VII. Evidence**

**A. Introduction**

This summary represents the body of evidence for PR for chronic obstructive pulmonary disease (COPD), asthma, bronchiectasis, ventilator dependency and other diseases in Medicare Beneficiaries. Health outcomes of interest to CMS for these indications include changes in mortality, modifiable risk factors, quality-of-life measures, and intermediate psycho/physiologic outcomes. Some of the common outcome measures examined in PR are Quality of life (QoL), functional exercise capacity, survival, and Activities of Daily Living (ADLs). Disease-specific QoL in COPD patients is commonly measured with the St George's Respiratory Questionnaire (SGRQ) and Guyatt's Chronic Respiratory Questionnaire (CRQ). Common measures of exercise capacity are the 6-minute walking distance (6MWD, expressed in meters) and the Shuttle Walking Test (SWT) that requires patients to walk at increasing speeds up and down a 10m course.

We also reference the GOLD (GOLD 2001) classification of COPD. This system classifies COPD patients into 3 classes as follows:

I: Mild COPD = FEV1/FVC < 70%, FEV1 ≥ 80% predicted.
With or without chronic symptoms (cough, sputum production)

II: Moderate COPD = FEV1/FVC < 70%, FEV1 ≥30% to ‹80% predicted

IIa: FEV1 ≥ 50% to < 80% predicted

IIb: FEV1 ≥ 30% to < 50% predicted
With or without chronic symptoms (cough, sputum production, dyspnea)

III: Severe COPD = FEV1/FVC < 70% FEV1 < 30% predicted or FEV1 < 50% predicted plus respiratory failure or clinical signs of right heart failure

This National Coverage Analysis (NCA) focuses on the following question:

- In persons age 65 years and older, is the evidence sufficient to conclude that PR and/or its components will improve health outcomes for COPD or other indications in the home, outpatient and CORF settings?

**B. Discussion of evidence reviewed**

**1. Literature Search**

CMS searched the Cochrane Library and Pubmed (1995 to present) databases for systematic reviews and technology assessments of pulmonary rehabilitation as well as randomized clinical trials (RCTs) evaluating pulmonary rehabilitation for persons 65 years of age and older. General keywords included pulmonary rehabilitation and randomized control trials. Studies must have presented original data, included ≥ 10 patients in each arm and been published in peer-reviewed English language journals. Abstracts were excluded.

**2. External technology assessments**

***Cochrane Collaboration Review of Pulmonary Rehabilitation (PR) for COPD (2006)***

This Cochrane meta-analysis was based on 31 RCTs for which health-related quality of life (QoL) and/or functional exercise capacity (FEC) or maximal exercise capacity (MEC) were measured in patients with COPD. This updated Cochrane collaboration review states that the primary conclusions of their prior review in 2001 were essentially strengthened in this update and they addressed several new issues. They concluded that there was significant benefit from respiratory rehabilitation including at least four weeks of exercise training as part of the spectrum of management for patients with COPD. The authors also found clinically and statistically significant improvements in the important domains of quality of life, including dyspnea, fatigue emotional function and mastery. Lastly they found that when compared with the treatment effect of other important modalities of care for patients with COPD such as inhaled bronchodilators or oral theophylline and its new derivatives, pulmonary rehabilitation resulted in greater improvements in important domains of health-related quality of life and functional exercise capacity.

***AHRQ Technology Assessment of Pulmonary Rehabilitation for COPD and other lung diseases (2006)***

This Technology Assessment defined PR as any intervention that included an exercise-training component of at least two weeks' duration and optionally one or more non-exercise components: educational, psychosocial support, breathing exercises, respiratory muscle training, or nutritional interventions. The TA analyzed 44 RCTs included in three published systematic reviews, and 26 additional RCTs that had not been assessed by these reviews. One of the inclusionary requirements was that the average age of participants was 59 years or more, while another was that the intervention contained an exercise regimen of at least two weeks duration.

The AHRQ TA excluded RCTs when the non-exercise PR components of the RCT were considered supplemental interventions. These were defined as pharmacological (e.g., $O_2$ supplementation during exercise, tiotropium administration during the PR etc.), nutritional (e.g. polyunsaturated fatty acids administration) or other interventions (e.g. ventilation support) aiming to facilitate or enhance the effects of exercise training.

Since PR cannot generally reverse the derangement of pulmonary mechanics (as assessed by $FEV_1$, other lung volumes and lung capacities) changes in pulmonary physiologic measurements were not reviewed in the TA.

The AHRQ TA utilizes the GOLD classification for COPD and we have utilized that classification in our NCD.

The authors concluded that exercise-based PR is effective in improving the patients' disease-specific QoL, as well as their functional and maximal exercise capacity. This was especially true in the short term (weeks to months) where the improvements were significant. Exercise-based PR interventions may reduce hospitalizations and primary care consultations. There is evidence supporting exercise-based PR among patients recovering from or recently recovered from acute exacerbations of COPD. The RCTs and meta-analyses did not provide evidence on the safety of PR interventions nor point out which co-morbid conditions predispose patients to or protect patients from adverse events. There is insufficient evidence to draw robust conclusions on whether exercise training has an incremental impact when added to non-exercise PR components like education or inspiratory muscle training. The authors reported not finding statistically significant differences when comparing exercise training alone with non-exercise components alone, and they did not find statistically significant differences when assessing the incremental impact of non-exercise components added to exercise training. Lastly, none of the above results translated to improved survival, at least among patients with stable COPD.

As a final comment the authors stressed that all the aforementioned results should be viewed with caution because they are based on relatively few studies of substantial sample size with good methodological strength.

**3. Internal technology assessment**

CMS independently searched PubMed for randomized controlled trials and selected trials in which PR was utilized. In this section, we do not review the studies that were extensively reviewed in the TAs above. Twelve relevant RCTs not included in the TAs were identified and are summarized below.

**Interventions Involving Exercise**

*Intervention: nurse-assisted patient education and self-management, and follow-up.*
*Setting: home*
Coultas et al. (2005)

This study was aimed at measuring the effect of increasing access to selected components of PR in COPD patients, namely patient education, enhanced follow-up, and enhanced patient self-management skills over a six-month period. The three arms were medical management (MM), nurse-assisted collaborative care (CM) and usual care (UC) with 51, 49, and 51 patients completing the study in each arm respectively (out of 217 enrollees total). Patients all had a $\geq$20 pack-year smoking history and were all $\geq$ 45 years of age with an average age of 69 years. There were no significant differences in demographics at baseline with the exception of age ($p<0.05$) being higher in the control group, though educational level approached significance ($p<0.07$, group data not shown). Outcomes were measured via the SF-36 and disease-specific SGRQ questionnaires. Findings demonstrated no significant differences when comparing the results of the three arms. Authors concluded that interventions in patient education, enhanced follow-up, and enhanced patient self-management skills in patients with COPD do not result in clinically meaningful improvements in health-care status and self-reported health care utilization. The large number of enrollees that dropped out of each group may have made the results skewed since they had more severe airflow obstruction, higher distress levels and lower QoL than the patients who completed the study. Data on demographics were not reported.

*Intervention: low- and middle-intensity PR exercise programs*
*Setting: home*
Bjornshave et al. (2005)

This report compared two frequencies of home-based training over a four-week period in 20 patients with moderate to severe COPD over an 18 month enrollment period. The original group was 124 patients of whom 65 were selected and only 20 accepted, nine in one group and 11 in the other (lower intensity) group. Demographic analysis showed no significant differences between the different arms on sex, age, and BMI, the only demographic characteristics listed in the paper. The outcome measured was walking time in seconds on a standardized treadmill test. Middle-intensity was significantly improved over low-intensity in percent improvement (55% versus 20%, $p<0.001$). The authors concluded that middle-intensity training increases the physical working capacity for patients.

*Intervention:* individually tailored walking and arm exercise in housebound COPD patients.
*Setting: home*
Boxall A et al. (2005).

Sixty homebound patients ≥ 60 years of age with COPD were studied over 12 weeks with either an individually tailored supervised walking and arm-exercise program plus patient education, or no intervention (until 12 weeks later for ethical reasons). Patient demographics comparisons showed no significant differences between study arms at the end of 12 weeks. Outcomes were measured by 6MWT results, the St. Georges Respiratory questionnaire and the Borg subjective breathlessness score. Significant results were an improvement in the Borg score ($p<0.024$), the St. Georges respiratory questionnaire score ($p<0.020$), and the 6MWT of the intervention group ($P<0.023$) as compared to the control group. At six months the intervention group demonstrated a shorter hospital length of stay (LOS) for readmission with exacerbation ($P<0.035$). The authors concluded that a 12 week home-based PR program is effective in improving exercise intolerance, subjective breathlessness, and QoL for housebound elderly COPD patients.

*Intervention:* PR for 4 weeks versus 7 weeks.
*Setting:* Outpatient
Green RH et al. (2001)

In this RCT forty four persons with COPD, 28 men and 16 women, average age 68, completed either a four week (N=23) shortened PR program or a conventional seven week PR program (exercise and disease education). The two groups were not statistically different on demographic characteristics. The subjects were measured before and after intervention on the CRQ (the primary outcome variable), the Breathing Problem Questionnaire (BPQ), the shuttle walking test (SWT) and the treadmill endurance test (TET). Clinical and statistical significance was reached for the total CRQ score in favor of the seven-week group ($p<0.05$) and its domains for dyspnea ($p<0.05$), emotion ($P<0.005$) and mastery ($P<0.05$). The authors concluded that a seven-week PR program provides greater benefits than a four-week PR program in terms of health status.

*Intervention:* Dyspnea management (DM) versus DM plus supervised exercise training.
*Setting:* Outpatient
Carrier-Kohlman et al. (2005)

In this RCT 103 patients (average age 66, F:M ratio=57:46) were randomized to one of three arms consisting of dyspnea self-management only (DM=individualized education and demonstration of dyspnea self-management strategies and bi-weekly nurse telephone calls), DM plus four supervised exercise sessions (DME) or DM plus 24 supervised exercise sessions (DMT). Outcomes were measured every two months for one year and consisted of dyspnea degree (Borg test) during incremental treadmill testing and on exercise performance on incremental and endurance treadmill tests at six and 12 months. Dyspnea on ADL and self-reported physical functioning (CRQ, SF-36) improved for all groups with DMT better than DME or DM as time went on. This was attributed by the authors to continuing supervised exercise sessions. DME and DMT were not significantly different from DM or each other at the end of one year. The authors reported missing data on 24 of 103 patients and an additional 12 patients dropped out before the first two-month period. The authors concluded that the greater the number of supervised exercise training sessions, the more improved ADLs and physical functioning would be for patients with COPD.

*Intervention:* Nutritional enhancement of exercise plus PR versus PR
*Setting:* Outpatient

Steiner MC et al. (2003)

In this study 85 persons with COPD were randomized to receive a carbohydrate supplement or non-nutritive placebo daily during a seven-week outpatient PR program (endurance, low impact conditioning, education). There was no statistically significant difference between groups on demographics at baseline with average age of 66-68 years and F:M ratio approximately 3.5:5 in both groups. Peak and submaximal exercise performance as well as walk tests, health status, body composition, muscle strength and macronutrient intake were measured. The results showed that both groups increased walking and health status significantly but the improvement in incremental shuttle walking test performance was significantly greater in the supplemented group ($P<0.05$). The placebo group lost weight while the treatment group gained weight. The authors concluded that exercise training results in negative energy balance that can be overcome by nutritional supplementation.

*Intervention:* drugs only versus drugs plus intensive PR
*Setting:* Outpatient
Guell R et al. (2006)

The impact of PR on psychosocial morbidity in patients with severe COPD was studied in this RCT where both arms were treated with salbutamol, ipatropium bromide, and inhaled budespniode (before admission to the trial), and one arm had additional intensive PR for four months (relaxation, various breathing exercises, chest and abdominal wall exercise). Forty male COPD patients with a mean age of 65, all having severe chronic outflow limitation, were randomized to a control group or to a PR group. Five dropped out leaving 18 in the intensive PR group and 17 in the control group. Outcome measures were psychological assessment using the MHBI (Million Behavioral Health Inventory), the Revised Symptom Checklist (SCL-90-R), the 6MWT, and the Chronic Respiratory Questionnaire (CRQ) for HRQL. At four months the PR group showed statistically significant improvements relative to the control group on the MBHI in selected scales of personality (forceful, sensitive, introversive and chronic tension $P<0.05$). The PR group also had statistically significant improvements relative to the control group on the SCL-90-R, in the selected scales of somatization, depression, anxiety, hostility, and total score ($p<0.01$), and in HQRL as measured by the CRQ, in the domains of dyspnea ($p<0.01$), and mastery ($P<0.05$). Finally, the PR group showed a statistically significant improvement in the 6MWT with a 63 meter increase as compared to a 22 meter decrease in the control group ($p<0.01$). The authors concluded that PR may decrease psychosocial morbidity in COPD patients even when no specific psychological intervention is performed. They also reiterated that PR has a positive impact on functional exercise capacity and HRQL.

**Interventions Involving Counseling with or without PR**

*Intervention:* individual counseling plus PR versus PR alone in COPD patients
*Setting:* Outpatient
De Blok et al. (2006)

This RCT in COPD patients studied the effects of a lifestyle physical activity counseling program in addition to a PR program (exercise training, dietary intervention, psycho-educational modules) versus the PR program only. Measurement with a pedometer during PR in 21 patients with COPD was studied in this pilot RCT (ten in the intervention group and 11 in the PR only group). Demographic characteristics were not reported in the paper except to say that patients were between 40 and 85 years of age, and from all stages of COPD. The primary outcome was the number of steps per day as measured by a pedometer. Secondary outcomes measured were depression status, HRQL, ADL, and self-efficacy. No statistically significant findings were reported though the exercise counseling group showed a p value of 0.11 in steps per day increase after nine weeks of the program. The intervention group wore the pedometer for ten weeks and the control group only the first and last weeks. The authors concluded, in spite of the very small sample sizes with resulting inability to correct for confounding variables, that the use of a pedometer is a feasible addition to PR with resulting improvement in outcome and maintenance of PR results.

*Intervention:* PR plus psychotherapy versus PR only
*Setting:* Outpatient
De Godoy et al. (2003)

An intervention group of 14 persons with COPD attended a PR program (physical exercise, physiotherapy, education) with one psychotherapy session per week and the control group (CG) of 16 persons had the same PR without psychotherapy in this RCT to test for the effect of psychotherapy on anxiety and depression in COPD. The patients averaged 60+ years of age and demographic differences between groups were not significant, apparently due to the small sample size (TG 14, CG 16). Males comprised the majority of both groups. Main outcomes were measured at inception and completion of 12 weeks of therapy using the Beck Anxiety Inventory (BAI) and the Beck Depression Inventory (BDI) as well as the 6MWD. Both groups showed statistically significant improvement on the 6MWD, while only the TG had significant reduction in anxiety ($p<.001$) and depression ($p<0.02$) levels. The authors concluded that including psychotherapy in a PR program for patients with COPD reduced anxiety and depression levels but did not impact 6MWD performance. The potential confounders in this study were not able to be adjusted for due to the small sample size.

*Intervention:* Shortness of breath education versus education on topics not related to lung disease.
*Setting:* Outpatient
Sassi-Dambron DE et al. (1995)

In this RCT 98 subjects with COPD were randomized to shortness of breath education for six weeks (education re: pulmonary physiology, COPD, dyspnea, progressive muscle relaxation, breathing techniques, panic control and stress management - TG) or health education on topics not directly related to lung disease (CG) with nine dropouts before treatment (one in the TG), and nine more during the treatment period (five in TG, four in CG). Outcome measures consisted of dyspnea measures (Borg, ATS dyspnea scale, Visual Analog Scale, baseline and transition dyspnea indices, and oxygen cost diagrams), and exercise tolerance (6MWD). At six weeks there was no significant difference between the TG and the CG on any outcome measure. The authors concluded that dyspnea management without structured exercise training or other PR program components does not improve exercise tolerance, dyspnea, HQRL, anxiety or depression.

*Intervention:* PR versus brief advice or education.
*Setting:* Outpatient

1) White RJ et al. (2002)

In this RCT 103 patients with COPD were randomized to receive either a six-week PR program two times per week at the hospital or to attend one advice session where they were given educational materials, verbal advice and guidance about exercise. The PR program consisted of walking, step and strengthening exercise plus education with regard to respiratory problem management. At three months they were reassessed on their original tests leading to before-after comparison. The average age in the two groups was 67 years and the M:F ratio was approximately 2:1 in both groups. The TG (N=54) six-minute walking distance increased significantly ($p<0.001$) by 43 meters as compared to 23 meters in the brief advice group (N=49), but there was no difference in the two groups in HRQL as measured by the CRQ. The authors concluded that even a short PR program was beneficial in terms of improved exercise tolerance as compared to brief advice.

2) Ries AL et al. (1995)
*Setting:* Outpatient

Over an 18 month period 352 patients with COPD were screened and 119 met the inclusion criteria and remained in the study (15 women and 42 men in the TG and 17 women and 45 men in the CG). The average age for the TG was 61 years and for the CG it was 63 years. All were on medical treatment. There were no significant demographic differences between the two groups at study entry. These subjects were then randomly assigned to either comprehensive PR (TG) or an education program (CG) over eight weeks. The PR program consisted of twelve four-hour sessions with education, physical and respiratory care instruction, psychosocial support and supervised exercise training. The education group attended four two-hour educational sessions with no individualized instruction or exercise training. Each subject was pre- and post-tested on physiologic and psychosocial function up to 72 months post intervention. Physiologic tests consisted of pulmonary function, maximum exercise tolerance (MET), endurance exercise and rest and exercise gas exchange. Psychosocial measures consisted of a self-efficacy questionnaire, a quality of well-being scale, the Centers for Epidemiologic Studies Depression Scale (CES-D) and the University of California SD shortness of breath (SOB) questionnaire. Results demonstrated that the eight week PR program produced significantly greater improvement in exercise endurance, MET, symptoms of perceived breathlessness, reported SOB, and self-efficacy for walking (all $p<0.05$). These benefits persisted for between six and 24 months after the intervention. There were no significant differences between groups in pulmonary function, depression or general QoL. The authors concluded that there were definite benefits of pulmonary rehabilitation with COPD in the areas of exercise endurance, MET, symptoms of perceived breathlessness, reported SOB, and self-efficacy for walking in a comprehensive PR program as compared to education only.

**4. MEDCAC**

Not applicable.

**5. Evidence-based guidelines**

The joint ACCP/AACVPR Evidence Based Guidelines regarding PR released in May 2007 provides a systematic, evidence-based review of the pulmonary rehabilitation literature that updates the 1997 ACCP/AACPR guidelines. The joint statement strengthens the 1997 recommendations. Specifically, ACCP/AACPR reaffirms health-related QoL improvements for pulmonary rehabilitation patients and supports improvements in health care utilization. The 2007 guidelines introduce new evidence supporting longer term rehabilitation, maintenance strategies following rehabilitation, the incorporation of education and strength training. Additionally, some support for noninvasive ventilation in selected patients with advanced COPD was demonstrated. And current evidence appears to benefit patients with chronic lung diseases other than COPD such as asthma, interstitial disease, bronchiectasis, cystic fibrosis, chest wall diseases, neuromuscular disorders, ventilator dependency, and before and after lung surgery for transplantation, volume reduction, or cancer. The joint statement does point out that current evidence does not support routine inspiratory muscle training, the use of anabolic drugs, nutritional supplementation, routine inspiratory muscle training and supplemental oxygen therapy for patients with severe hypoxemia.

The major national and international respiratory organizations (ATS/ERS, the American College of Chest Physicians [ACCP] jointly with the American Association of Cardiovascular and Pulmonary Rehabilitation [AACVPR], and Global initiative for chronic Obstructive Lung Disease) have recommended PR as the standard of care in the treatment of moderate to severe chronic respiratory disease and these represent GOLD classification II or III (moderate or severe) COPD (Gold 2001).

**6. Professional Society Position Statements**

The ACCP/AACPVR joint statement states that there is substantial new evidence to support that PR is beneficial for patients with COPD and other chronic lung diseases. They cite current research and opportunities for future research that will possibly advance the current state of knowledge and make PR available to many more eligible patients.

The ATS/ERS joint statement notes that PR has become recognized as a cornerstone in the comprehensive management of patients with COPD. They cite that the evidence for improvement in exercise endurance, dyspnea, functional capacity, and quality of life is stronger for rehabilitation than for almost any other therapy in COPD. Additionally, PR has a favorable influence on systemic effects and comorbidities associated with chronic lung disease. Suggesting that because these impairments are present to some extent in all chronic lung disease PR should be effective in diseases other than COPD. However, they note that more research is needed to optimize the effectiveness of PR and implementation strategies should be aimed at improving availability to all patients needing it, especially through involving health care professionals as to rational, scope and benefits of PR. The statement suggests that adjunctive strategies, such as hormonal therapy, supplemental oxygen administration to non-hypoxemic patients, and noninvasive ventilation, are being developed; but their effectiveness must be established. Additionally, PR effectiveness in respiratory diseases other than COPD must be established through clinical trials. Finally, they note that there exists a need to develop ways to maintain the benefits of PR, especially through improving long-term self-management and adherence to the exercise regimen in the home setting and more concerted efforts are needed to evaluate the effect of PR on survival, because it is entirely possible that it may favorably influence this outcome.

The AARC published a clinical practice guideline for PR. Although the type of supporting evidence is not specifically stated for each recommendation, the guideline is developed from a thorough review of the literature, surveys of current practice, and the expertise of the members of their working group.

The guideline defines PR as a "multi-disciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and autonomy." They acknowledge that PR provides multidisciplinary training to improve the patient's ability to manage and cope with progressive dyspnea. PR efforts are often focused on patients with chronic obstructive pulmonary disease (chronic bronchitis and/or emphysema), other conditions appropriate for this process include, but are not limited to, patients with asthma, interstitial disease, bronchiectasis, cystic fibrosis, chest wall diseases, neuromuscular disorders, ventilator dependency, and before and after lung surgery for transplantation, volume reduction, or cancer.

PR services include critical components of assessment, physical reconditioning, skills training, and psychological support. Additional PR services may include vocational evaluation and counseling. A PR program must be tailored to meet the needs of the individual patient, addressing age-specific and cultural variables, and should contain patient-determined goals, as well as goals established by the individual team discipline. Both patients and families participate in this training administered by health care professionals. PR services are overseen by a medical director to assure appropriate performance by the program staff and to assure proper service delivery for patients with chronic respiratory disease.

Based on the individualized assessment, areas that should be considered are: pulmonary anatomy and physiology including the pathophysiology of lung disease; description and interpretation of medical tests; bronchial hygiene techniques; exercise conditioning and techniques including: breathing retraining and endurance, strength, and flexibility training of the upper and lower extremities.

Other areas that should be included in the assessment include actions and side-effects of medications including non-prescription products, such as vitamins, over-the-counter medications, and herbal remedies; functional self-management; sleep disturbances; sexuality and intimacy; nutrition; smoking cessation counseling; psychosocial intervention and support; available community services, including patient/family support groups; advance care planning; travel issues; recreation/leisure activities; stress management and indications for oxygen and methods of delivery.

**7. Expert Opinion**

CMS received no comments identified as expert opinions during the initial 30-day comment period.

**8. Public Comments**

During the initial 30 day public comment period, CMS received 154 comments. The majority of the comments did not address any of the five questions posed on the CMS tracking sheet. Comments that directly addressed the five questions we asked included four comments from professional societies, one comment from a voluntary health organization and five comments from hospitals that provide PR services on an outpatient basis. The full summary of those comments can be found in our proposed decision memorandum on our coverage website. CMS proposed on June 27, 2007, “that the respiratory therapy services identified in the Comprehensive Outpatient Rehabilitation Facility (CORF) as defined in 42 CFR §410.100(e)(1) to (2)(vi) are reasonable and necessary in chronic obstructive pulmonary diseases (COPD) in patients with GOLD classification II or III (moderate or severe) when furnished under a written plan of treatment that considers all respiratory therapy services.”

Summary of Comments on Proposed Decision Memorandum

CMS received 160 public comments, universally in favor of national coverage for pulmonary rehabilitation. Of these comments, 101 were patients and five were family advocates of patients, who submitted as their basis for national coverage the increased well being, psychologically and physically, of those who engage in pulmonary rehabilitation. Twenty five comments submitted by the EFFORTS (Emphysema Foundation for our Right to Survive) organization related to improved quality of life, as well as psychological and physical well-being. There were comments from 25 hospitals or rehabilitation facilities largely touting the cost-saving benefits of pulmonary rehabilitation and the majority of them cited decreased hospital stays and reduced use of other related services. Four organizations submitted detailed comments related to the positive health benefits of pulmonary rehabilitation and/or the correlated need for national coverage to provide access to all. Many comments reflected the view that a national coverage policy would provide consistent coverage across geographic lines and should be implemented. However, we have determined that no national coverage determination is appropriate at this time, and that decisions pursuant to § 1862(a)(1)(A) should be made by local contractors through the local coverage determination process or by case-by-case adjudication.

We specifically requested comments which addressed our proposed decision and particularly requested input on the frequency and/or duration of the respiratory therapy services identified in 42 CFR 410.100(e) (1) to (2) (vi). Of the 160 comments, 14 addressed the frequency and duration question posed in the proposed decision memo. The range of the provision of sessions and services varied greatly. Frequency ranged from two times per week up to three times per week for durations ranging from six through thirty sessions. However, no outcome data were provided to support a correlation between the duration and frequency of services and positive outcome results.

A. Professional Societies

**Comment:** The American Physical Therapy Association (APTA) expressed concern regarding the possible misinterpretation by Medicare contractors of CMS's decision, specifically, "While we appreciate CMS' thorough decision regarding coverage of pulmonary rehabilitation , we are concerned that this decision could be misinterpreted by Medicare contractor as an indication that they should rescind current local coverage polices that enable Medicare beneficiaries to obtain essential pulmonary rehabilitation services provided by physical therapists. Therefore, we believe it is essential for CMS in its decision to make clear in its final decision memorandum that Medicare contractors should not eliminate existing policies that provide coverage for these critical services…"

**CMS Response:** CMS has determined that no NCD is appropriate at this time and therefore, local contractors retain their discretion to allow coverage for components of pulmonary rehabilitation, including services furnished by physical therapists under section 1861(p) of the Social Security Act.

**Comment:** The APTA further recommends that, "CMS issue letters of clarification to local contractors stating that decision not to promulgate a national coverage decision should in no way alter or affect the current LCDs on Pulmonary Rehabilitation Services as promulgated by the carriers and fiscal intermediaries."

**CMS Response:** Given that CMS has determined that an NCD is not appropriate at this time, we do not believe that issuing a written clarification is necessary.

**Comment:** The American Association for Respiratory Care (AARC) offered to gather further data to support a national coverage decision for pulmonary rehabilitation as a Part B benefit. They proposed a meeting with CMS to "discuss specific ways in which they can assist the agency towards this goal and/or asset with the development of proposed regulations in the event the current legislative proposal is passed into law".

**CMS Response**: Future data collection and legislation are outside the scope of this final decision memorandum.

B. General Public Comments

**Comments:** Several comments without evidence asserted extreme positive benefits of pulmonary rehabilitation. One commenter stated that the use of pulmonary rehabilitation slows the progression of the disease. Three commenters, all afflicted with COPD, maintained that pulmonary rehabilitation saved their lives. An employee at Aurora Medical Center who started two pulmonary rehabilitation programs there reported seeing "great results in patient's knowledge of their lung disease and their everyday living." She cited the case of "one patient who quit smoking due to the support of rehab program and the better understanding of his lungs and what smoking was doing to them."

**CMS Response**: While these testimonials are encouraging, no additional evidence was cited to support the comments submitted. While we take into account all comments received, we accord substantially less weight to those without supporting evidence. As we indicated, local contractors may continue to make decisions under § 1862(a)(1)(A), with regard to services related to pulmonary rehabilitation, through the local coverage determination process or on a case-by-case basis.

**Comment:** Inova Fairfax Hospital disagrees with the CMS proposed decision memo, based on their belief that (1) there is scientific evidence to support coverage and (2) CMS is applying an inconsistent application of the principles of the "not reasonable and necessary" exclusions, based on Pulmonary Rehabilitation not being expressly defined in the Social Security Act (the Act). They maintain that there is evidence related to the BODE index as a predictor of mortality in COPD, and there are half a dozen other surgeries or programs for which CMS allows coverage which are also not defined in the Act.

**CMS Response:** We consistently apply a "reasonable and necessary" standard based on our review of scientific and clinical evidence to determine if it is adequate to support national coverage. Although we believe there is some evidence as to the benefits of pulmonary rehabilitation, we believe the evidence is not adequate to draw conclusions about the frequency or duration of the respiratory services identified in 42 C.F.R. 410.100(e)(1) to (2)(vi) for Medicare beneficiaries with COPD as we proposed. In addition, due to the variety of potential settings for the provision of the components of pulmonary rehabilitation and the various individually applicable benefit categories, we are not able to specifically elaborate on the circumstances under which limited coverage is permissible. In the absence of such specificity we refer you to section III of this memo for guidance and to the interpretation by local contractors.

**Comment:** Other comments included were from the academic field, one from an emeritus clinical professor from the University Of California, San Francisco, Medical School and who is also an adjunct professor from Stanford Medical School. He provided the following comment, in part: "The current law is not specific enough to cover the needs of patients with COPD and legislation should include complete coverage for this major need."

**CMS Response**: Any issue pertaining to new legislation or legislative changes is outside of the scope of this decision memorandum.

**Comment:** A pulmonary rehabilitation coordinator from University Hospital Geauga Medical Center expressed the view that is "plainly discrimination" that "cardiac patients receive 36 sessions after an event while pulmonary disease patients receive only 30 sessions", and "must wait until their illness reaches significant disability before Pulmonary Rehab is indicated."

**CMS Response**: The cardiac rehabilitation sessions referred to were the subject of a different NCD, based on CMS's evidence review regarding the number of sessions. Decisions regarding the number of sessions may vary depending on the disease and should be evidence-based. CMS determined that the evidence is not adequate to draw conclusions about the frequency or duration of respiratory therapy services in a CORF; therefore we are not making any national coverage determination at this time.

**Comment:** An advocate from the Hawaii COPD Coalition expressed dismay and strong concern that without national coverage "patients and their medical providers will need to tiptoe around to try to find the right wording and jurisdictions to get patients any services they need, including the need to cross state lines to places which might have less confusing and conflicting local determinations."

**CMS Response:** Most Medicare coverage is local coverage and this decision does not require alteration of any LCDs.

C. Comments with Evidence

The two references below provided through public comments as new evidence not considered in the proposed decision memorandum:

Ries AL, Make BJ, Lee S, Krasna M, Bartels M, Crouch R, Fishman A, the National Emphysema Treatment Trial Research Group. The Effects of Pulmonary Rehabilitation in the National Emphysema Treatment Trial. Chest. 2005 Dec;128(6):3799-809.

Ries AL, Bauldoff GS, Carlin BW, Casaburi R, Emery CF, Mahler DA, Make B, Rochester CL, Zuwallack R, Herrerias C. Pulmonary Rehabilitation: Joint ACCP/AACVPR Evidence-Based Clinical Practice Guidelines. Chest. 2007 May;131(5 Suppl):4S-42S.

The first article provides information on the effects of on pre- and post-operative services on surgical patients with advanced emphysema and is outside the scope of this decision. The second was not yet published at the time of the proposed decision but was cited in the proposed decision memorandum (Section VII.B.5 above) based on an advance copy of the publication.

**Comment:** Frazier Rehabilitation submitted information regarding a study in which their facility participated. Twenty four patients with restrictive lung disease were treated with pulmonary rehabilitation and evaluated based on 55 outcome parameters. No outcomes showed worsening, twenty six showed statistically significant improvement and fourteen subgroups showed clinically significant improvement. They suggested that we should cover the pulmonary rehabilitation services for patients with restrictive lung disease. They also advocated for coverage of pulmonary rehabilitation for pre-lung transplant patients.

**CMS Response:** The cited study was published only in abstract form in 2002 in the Journal of Cardiopulmonary Rehabilitation. Abstracts generally are accorded less weight than material that has been subject to rigorous peer review and published in recognized medical journals. While we believe there may be benefits from pulmonary rehabilitation for restrictive lung disease, CMS did not find adequate evidence to draw conclusions about restrictive lung diseases.

With regard to pre-lung transplant patients, no evidence was provided to support coverage.

**VIII. CMS Analysis**

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” § 1862(a)(1)(A).

***Definition and Components of Pulmonary Rehabilitation***

All of the professional societies except for APTA cite the definition adopted in the ATS and the European Respiratory Society (ERS) 2006 Statement on Pulmonary Rehabilitation: “Pulmonary rehabilitation is an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease.” We believe that this is a reasonable definition for pulmonary rehabilitation services. We believe this is a reasonable definition for pulmonary rehabilitation services. Although services that make up pulmonary rehabilitation individually may be covered under Medicare and fall into various applicable benefit categories, CMS has determined that the Social Security Act does not expressly define a comprehensive Pulmonary Rehabilitation Program as a Part B benefit.

In our review of the literature, the components of PR did vary. However, they generally include some or all of the following components: a medical evaluation, treatment plan development and implementation, monitoring, counseling/ education; exercise training; self-management training; nutrition training; and psychosocial support (Nici et al., 2006). As the TA and our internal assessment found, there is strong evidence to support exercise as an effective component of PR. There is a paucity of evidence regarding drawing robust conclusions on whether exercise training has an additional impact when added to other non-exercise PR components such as counseling, education or inspiratory muscle training. Part of the reason for the paucity of data is that, while there is general agreement on what the components of PR are, there is little agreement on how to standardize, measure and test the effects of the combinations of components. This has resulted in many RCTs that do not measure the same thing. Though there is generally a lack of statistically significant differences when comparing exercise training alone with non-exercise components alone, and when assessing the incremental impact of non-exercise components added to exercise training, we did find evidence to support counseling by a health care specialist in certain specified situations (De Blok et al. (2006), De Godoy et al. (2003), Steiner MC et al. (2003), White RJ et al. (2002)). There is generally insufficient evidence to draw robust conclusions on whether education or inspiratory muscle training has an incremental impact when added to exercise training.

The vast majority of evidence was found for PR in outpatient settings. For home-based PR, interventions such as patient education, enhanced follow-up, and enhanced self-management skills in patients with COPD did not result in clinically meaningful improvements in health care status and self-reported health care utilization. However, Boxall et al. reported that in homebound patients $\geq$ 60 years of age with COPD, a 12 week home-based PR program was effective in improving exercise intolerance, subjective breathlessness, and QoL for housebound elderly COPD patients. Overall we found insufficient evidence to support homebound PR programs or components.

A large number of randomized controlled trials (RCT) have been reported on PR interventions in participants generalizable to the Medicare population, and most of these trials studied patients with COPD. The data we reviewed mostly applies to GOLD classification II or III (moderate or severe) COPD (Gold 2001) patients. CMS found strong evidence to conclude that that exercise-based PR is effective in improving the patients' disease-specific QoL, as well as their functional and maximal exercise capacity. This is especially true in the short term (under 12 weeks) where improvements are significantly larger than the accepted minimal clinically meaningful improvement. CMS also finds that exercise-based PR interventions may reduce hospitalizations and primary care consultations. PR is also supportive in patients recovering from or recently recovered from acute exacerbations of COPD. Therefore, the evidence is adequate to conclude that pulmonary rehabilitation improves health outcomes for persons with GOLD classification II or III (moderate or severe) COPD in ambulatory settings.

CMS did not find adequate evidence to draw conclusions about pulmonary diseases other than COPD. Therefore, we are not drawing any conclusions about the reasonableness or necessity of PR for these conditions.

The evidence also does not clearly delineate the appropriate frequency or duration of PR sessions. The AHRQ TA included RCTs that reported a variety of frequencies of exercise training, ranging from three times per week for six weeks up to five times per week for 12 weeks. Commenters provided anecdotal evidence supporting range of provision of PR sessions from two to three times per week and duration of six through thirty sessions, without substantial supporting evidence. Overall, the evidence is not adequate to draw conclusions about the frequency or duration of these services in any setting.

Having made these evidentiary conclusions, we must now apply these to the Medicare program. Respiratory therapy services covered in the CORF setting as defined in 42 CFR § 410.100(e)(1) to (2)(vi) are consistent with our evidentiary findings regarding pulmonary rehabilitation services (although services covered in a CORF do not include nutrition services).

In addition, while some of the components of pulmonary rehabilitation do have a benefit category, our evidentiary review did not find evidence of benefit when the services with a benefit category are provided independently to COPD patients. Thus, we are unable to make a reasonable and necessary decision on individual components of pulmonary rehabilitation provided in Medicare patients in other settings. Accordingly, we have determined that a national coverage determination is not appropriate at this time. Local contractors may continue to make decisions under § 1862(a)(1)(A), with regard to services related to pulmonary rehabilitation, through the local coverage determination process or on a case-by-case basis.

**IX. Decision**

On December 27, 2006, we initiated the national coverage determination (NCD) process by opening a tracking sheet for Pulmonary Rehabilitation (CAG-00356N). After examining the available medical evidence, we have determined that no national coverage determination is appropriate at this time, and that decisions pursuant to § 1862(a)(1)(A) should be made by local contractors through the local coverage determination process or by case-by-case adjudication. See Heckler v. Ringer, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003).

Although services that make up pulmonary rehabilitation individually may be covered under Medicare and fall into various applicable benefit categories, CMS has determined that the Social Security Act does not expressly define a comprehensive Pulmonary Rehabilitation Program as a Part B benefit. In addition, as we noted, respiratory therapy services are identified as covered services under the CORF benefit and defined in 42 CFR § 410.100(e)(1) to (2)(vi). In our proposed decision memorandum, we proposed to cover nationally those services identified in 42 C.F.R. § 410.100(e)(1) to (2)(vi) for Medicare beneficiaries with COPD. Furthermore, we requested comments on the frequency and duration of the respiratory therapy services identified in 42 CFR §410.100(e)(1) to (2)(vi). We have determined, however, that the evidence is not adequate to draw conclusions about the frequency or duration of these CORF services. Therefore, we are not making a national coverage determination at this time. Accordingly, local contractors may continue to make decisions under § 1862(a)(1)(A), with regard to services related to pulmonary rehabilitation, through the local coverage determination process or on a case-by-case basis.

**Appendices** [PDF, 325KB]
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# Bibliography

Anto JM, Vermeire P, Vestbo J, Sunyer J. Epidemiology of chronic obstructive pulmonary disease. Eur Respir J 2001; 17: 982-994.

Bjornshave B, Korsgaard J. Comparison of two different levels of physical training in patients with moderate to sever COPD. Lung 2005 183:101-108

Boxall A, et al. A randomized controlled trial of home-based pulmonary rehabilitation for elderly housebound patients. Jrnl Cardiopulm Rehab 2005;25:378-385

Carrier-Kohlman et al. Impact of brief or extended exercise training on the benefit of a dyspnea self-management program in COPD. Jrnl Cardiopulmon rehabil 2005;25:275-284

Cochrane Collaboration Review of Pulmonary Rehabilitation (PR) for COPD (2006)

Coultas D, Frederick M, et al., A randomized trial of two types of nurse-assisted home care for patients with COPD. Chest 2005; 128:2017-2024

De Blok et al., The effects of a lifestyle physical activity counseling program and feedback with a pedometer during PR in patients with COPD: A pilot study. Pt Educ and Counseling 2006: 61;48-55

De Godoy DV et al. A randomized controlled trial of the effect of psychotherapy on anxiety and depression in COPD. Arch Phys Med Rehabil 2003;84:1154-1157

Fletcher CM, Tinker CM, Peto R, Speizer FE. The natural history of chronic bronchitis and emphysema. Oxford, Oxford University Press, 1976.

Gold DR, Wang X, Wipyj D, Speizer FE, Ware JH, Dockery DW. Effects of cigarette smoking on lung function in adolescent boys and girls. N Engl J Med 1996; 335: 931-937

The GOLD Workshop Panel. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: NHLBI/ WHO Workshop Report. Bethesda, Md: National Heart, Lung, and Blood Institute; 2001. NIH Publication No. 2701.

Green RH et al. A randomized control trial of four weeks versus seven weeks of pulmonary rehabilitation in COPD. Thorax (2001);56:143-145

Guell R, et al. The impact of PR on psychosocial morbidity in patients with severe COPD. Chest 2006;129,4:899-904.

LaCasse Y, Goldstein R, Lasserson TJ, Martin S. Pumonary rehabilitation for chronic obstructive pulmonary disease. Cochran Collaboration. John Wiley & Sons, Ltd. 2006

Mannino DM, Homa DM, Akinbami LJ, Ford ES, Redd SC. Chronic obstructive pulmonary disease surveillance - United States, 1971-2000. MMWR 2002; 51: 1-16.

Nici L et al. American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation. Am J Respir Crit Care Med Vol 173. pp 1390–1413, 2006

Pulmonary Rehabilitation for COPD and other lung diseases. Agency for Healthcare Research and Quality.2006

Ries AL et al. Effects of pulmonary rehabilitation on physiologic and psychosocial outcomes in patients with COPD. Ann Intern Med. 1995 Jun 1;122(11):823-32.

Sassi-Dambron DE et al. A controlled clinical trial of dyspnea management strategies. Chest 1995;107:724-729

Steiner MC et al. Nutritional enhancement of exercise performance in COPD: a randomised control trial. Thorax 2003;58:745-751

White RJ et al. Pulmonary rehabilitation compared with brief advice given for severe COPD. Jrnl Cardiopulm Rehabil 2002;22:338-344

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